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10/722,968	11/26/2003	Li Ding	25629/16	9003

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EXAMINER

WILLIAMS, LEONARD M

ART UNIT	PAPER NUMBER
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1617

MAIL DATE	DELIVERY MODE
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09/07/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/722,968	Applicant(s) DING ET AL.	
	Examiner Leonard M. Williams	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
 4a) Of the above claim(s) 1-25 and 43-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 26-42 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/22/2006</u> . | 6) <input type="checkbox"/> Other: ____. |

Detailed Action

Election/Restrictions

Applicant's election with traverse of Group II claims 26-42 in the reply filed on 05/01/2007 is acknowledged. The traversal is on the ground(s) that there is no search burden in searching the composition and method claims concurrently. This is not found persuasive because the examiner has clearly detailed the reasoning behind the election restriction based upon the classification and the different statutory categories of invention.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Delrieu et al.

Delrieu et al. teach, in col. 4 lines 5-43:

“The invention, as claimed, is intended to provide a remedy for the problem of providing a delivery system for delivering labile and other actives to the skin, or other

body surface, for topical application in a cosmetic or pharmaceutical formulation. It furthermore solves problems of delivering actives that may react undesirably with the delivery system itself, damaging the active or causing stability problems with the formulation.

Accordingly, the invention provides a protective cosmetic particulate gel delivery system for a topically applied active agent comprising discrete gel particles formed of:

- a) an agar gel; and
- b) a restraining polymer dispersed in the agar gel, the restraining polymer having sufficient molecular weight to prevent egress of the restraining polymer from the agar gel, having retention groups to bind the active agent to the restraining polymer for retention in the gel particles and being present in a proportion sufficient to deliver an effective amount of the active agent; wherein the gel particles are manually crushable on the skin to increase the surface area of the gel particle material and expose the restraining polymer to the skin or other body surface for release of the active agent.

Preferably, active agent molecules are bound to the restraining polymer retention groups and the restraining polymer has an average molecular weight of at least 100,000 daltons. In a preferred embodiment, the active agent and the retention groups both comprise polar groups and are of opposite polarity whereby the active agent can bind ionically with the retention groups. A suitable restraining polymer is water-soluble and has a polysaccharide backbone substituted with strongly cationic quaternary ammonium groups which can act as retention groups for a range of active agents. The cationic ammonium groups are able to form stable ionic bonds with anionic actives which bonds

can be broken to release the active upon topical application of the containing cosmetic composition.

Delrieu et al. teach, in col. 5 lines 4-29:

"The invention also provides a method of preparing agar gel particles comprising the steps of:

a) dissolving agar in water heated to an elevated temperature sufficient to dissolve the agar, in a proportion of agar to water effective to form a gel at lower temperatures; and
b) mechanically dispersing the agar solution in a cold hydrophobic liquid immiscible with the agar solution maintained at a temperature below the agar gelling point;
with the improvement that a water-soluble restraining polymer is included in the agar solution whereby the drops are formed into gel beads incorporating the restraining polymer.

Preferably, though not necessarily, the hot agar solution to an intermediate temperature above the gelling point of the agar solution prior to performing step b). In a preferred embodiment, which is simple and economic to practice, the agar-restraining polymer solution is mechanically dispersed in the cold hydrophobic liquid by using a rotating agitator. Using this method, the gel bead size can be controlled by selecting the rotation speed of the agitator.

In an alternative embodiment, the agar-restraining polymer solution is mechanically dispersed in the cold hydrophobic liquid by injection through a hollow needle to form drops, the needle having an internal dimension selected to provide a desired gel bead size."

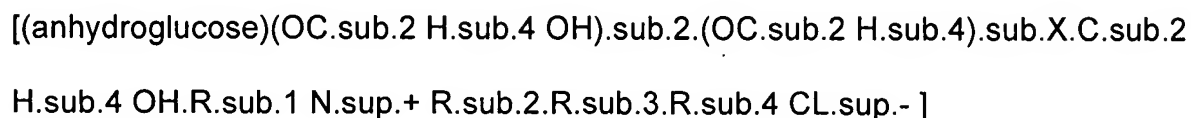
Delrieu et al. teach, in col. 8 line 64 to col. 9 line 60:

"Pursuant to the invention, it has been discovered that polymers with an average molecular weight of about 100,000 daltons, and more, are unable to flow through a preferred agar gel matrix. However, certain polymers, especially polymers capable of interacting with the agar, may be adequately retained in an agar gel, for the purposes of the invention even although they have a lower average molecular weight, e.g down to 75,000 daltons, or even as low as 50,000 daltons. There is no particular upper limit to the molecular weight of the restraining polymer, although it is contemplated that the average molecular weight will not exceed several million, e.g. 5 million daltons, but preferably does not exceed 1 million daltons. A preferred range for the average molecular weight is from 75,000 to 125,000 daltons.

Some preferred classes of restraining polymer are cationic polysaccharides and polypeptides or proteins. For example, some specific restraining polymers preferred for the practice of the invention are certain commercially available quaternized polysaccharides, especially celluloses, rich in quaternary groups, notably polyquaternium 24 available under the trademark QUATRISOFT LM-200 (Union Carbide Corporation), polyquaternium 11, available for example under the trade name GAFQUAT 755N (ISP Europe), and the CRODACEL Q (trademark) range of alkyl quaternary cellulose polymers (Croda, Inc.), notably laurdimonium hydroxyethylcellulose, sold under the trademark CRODACEL QL, cocodimonium hydroxyethylcellulose, sold under the trademark CRODACEL QM and steardimonium hydroxyethylcellulose, sold under the trademark CRODACEL QS. The CRODACEL Q

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(trademark) polymers belong to a class of polymers having repeating units of the following general nature:



where x is often unspecified but may be taken to be under 10 and may be 0; R.sub.1 is commonly methylene; R.sub.2 and R.sub.3 are frequently methyl and R.sub.4 is the characteristic longer alkyl group, e.g. 10-30 carbon atoms such as lauryl, cocoyl or stearyl. The polyquaternium 24 polymers lack the two hydroxyethyl substituents. Each anhydroglucose unit can have a maximum of three ethoxy substituents, as shown, but in practice, the average degree of ethoxy substitution will be substantially lower so that the indication of di-hydroxyethyl substitution should be regarded as a theoretical limit rather than a practical representation. Thus, each repeating anhydroglucose or saccharide unit contains up to two hydroxyethyl substituents and a quaternary ammonium group attached to the polysaccharide nucleus via a short polyethoxy chain. Polyquaternium polymers lack the longer alkyl group and the lipophilic character it confers.

Of particular importance is the quaternary nitrogen atom which provides a cationic binding site for anionic actives. The R.sub.4 alkyl chain can provide a lipophilic anchor for lipid or lipophilic actives. the CRODACEL Q (trademark) range of quaternized celluloses are more fully described in a product data sheet entitled "Crodacel Q range" from Croda Chemicals Ltd., UK, the disclosure of which is hereby incorporated herein by reference thereto. They are supplied as somewhat hazy or opaque viscous

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concentrates intended for dilution and are known as film-forming agents with particular application in hair shampoos and conditioners, where their ability to be substantive to the hair, i.e. to attach themselves to the hair in a substantive manner, without creating build-up, is valuable. These and similar polymers suitable for use in the practice of this invention are well known in the literature and are described, for example, in U.S. Pat. No. 5,135,748 (Ziegler et al.), U.S. Pat. No. 4,970,067 (Panandiker et al.), U.S. Pat. No. 5,288,484 (Tashjian) the disclosures of which are also hereby incorporated herein by reference thereto."

In col. 13 lines 24-30, Delrieu et al. disclose that the gel beads can be used in cosmetic compositions in concentrations of from 0.1-90 weight percent anticipating the "...method...wherein the gelling agent comprises about 1.5%...of claim 40.

In col. 14 lines 58-61, Delrieu et al. teach that the intermediate temperature is maintained at about 50°C. The office generally gives the term "about" a 10% range thus "about 50°C" is interpreted as 45-55°C.

In examples 1 and 2 the restraining polymer is present in the composition at a concentration of 1.5% by weight anticipating the "...method...wherein the restraining polymer comprises about 0.2 to about 7.5%..." of claim 34. In example 5 the restraining polymer is present in a concentration of 7.5% by weight and the FD&C Blue colorant is present in a concentration of 0.5% by weight of the composition anticipating "...method...comprising pre-dispersing a pigment..." of claim 39.

In example 15, Delrieu et al. disclose the use of 1.6g of silica shells (density-control agent) with an apparent density of 0.5-1.0 g/in³, 1.5g agar (gel bead), 1.5 g PG-

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hydroxyethylcellulose stearyldimonium chloride (restraining polymer), 10g dipropylene glycol and 97 g water. Giving 1.3% of a density-control agent (see applicant's specification page 11, lines 10-20 detailing silica as a density controlling microsphere), 1.3% of a restraining polymer and 1.3% of the gel bead agar anticipating the "...method of preparing density-controlled beads..." of claim 26, the "...method...comprising..." of claim 27, the "...method...wherein the gel beads have an average particle diameter of from about 0.1mm to 10mm" of claim 28, the "...method...wherein the first temperature is about 90oC" of claim 29, the "...method...wherein a water-soluble restraining polymer is included..." of claim 30, the "...method...wherein the restraining polymer has a molecular weight of at least 50,000 daltons..." of claim 32, the "...method...wherein the gel particles are manually crushable..." of claim 33, the "...method...wherein the restraining polymer comprises about 0.2 to about 7.5%..." of claim 34, the "...method...wherein the intermediate temperature is about 45oC..." of claim 35, the "...method...wherein the density-control agent is pre-dispersed in oil..." of claim 36, the "...method...comprising admixing..." of claim 37, the "...method...wherein the density-control agent comprises heat-expandable microspheres..." of claim 38, the "method...comprising pre-dispersing a pigment..." of claim 39, the "...method...wherein the gelling agent comprises about 1.5%..." of claim 40, the "...method...wherein the density-control agent comprises about 0.01% to about 5%..." of claim 41.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Delrieu et al. (US Patent No. 6319507).

Delrieu et al. is as set forth above.

Delrieu et al. does not teach density-control agents comprising about 0.02% to about 0.1%. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a variety of concentrations of a density-control agent as Delrieu et al. teach the use of a density-control agent and it is within the skill of one of ordinary skill in the art to adjust the concentration of density-control agents.

The examiner respectfully points out the following from MPEP 2144.05: "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969); *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed.Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

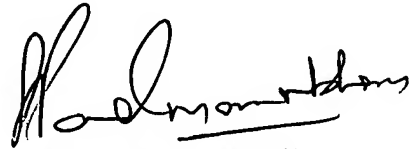
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leonard M. Williams whose telephone number is 571-272-0685. The examiner can normally be reached on MF 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LMW



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER